

Patient Information
Anastrozole (an-AS-troe-zole) Tablets, USP

What is the most important information I should know about anastrozole tablets?

Anastrozole tablets may cause serious side effects including:

- **heart disease.** Women with early breast cancer, who have a history of blockage in their heart arteries (ischemic heart disease) and who take anastrozole tablets, may have an increase in symptoms of decreased blood flow to their heart compared to similar women who take tamoxifen.

Get medical help right away if you have new or worsening chest pain or shortness of breath during treatment with anastrozole tablets.

What are anastrozole tablets?

Anastrozole tablets are a prescription medicine used in women after menopause (“the change of life”) for:

- treatment of early breast cancer
 - after surgery
 - in women whose breast cancer is hormone receptor-positive
- the first treatment of breast cancer that has spread to nearby tissue or lymph nodes (locally advanced) or has spread to other parts of the body (metastatic), in women whose breast cancer is hormone receptor-positive or the hormone receptors are not known.
- treatment of advanced breast cancer, if the cancer has grown, or the disease has spread after tamoxifen therapy

Anastrozole tablets does not work in women with breast cancer who have not gone through menopause (premenopausal women).

Who should not take anastrozole tablets?

Do not take anastrozole tablet if you:

- have had a severe allergic reaction to anastrozole or any of the ingredients in anastrozole tablets. See the end of this leaflet for a complete list of ingredients in anastrozole tablets. Symptoms of a severe allergic reaction to anastrozole tablets include: swelling of the face, lips, tongue or throat, trouble breathing or swallowing, hives and itching.

What should I tell my healthcare provider before taking anastrozole tablets?

Before you take anastrozole tablets, tell your healthcare provider if you:

- are still having menstrual periods (are not past menopause). Talk to your healthcare provider if you are not sure.
- have or had a heart problem
- have been told you have bone thinning or weakness (osteoporosis)
- have high cholesterol
- have any other medical conditions
- are pregnant or plan to become pregnant. Taking anastrozole tablets during pregnancy or within 3 weeks of becoming pregnant may harm your unborn baby.
 - Females who are able to become pregnant should have a pregnancy test before starting treatment with anastrozole tablets.
 - Females who are able to become pregnant should use effective birth control (contraceptive) during treatment with anastrozole tablets and for 3 weeks after your last dose of anastrozole tablets. Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

- are breastfeeding or plan to breastfeed. It is not known if anastrozole tablets passes into breast milk. Do not breastfeed during treatment with anastrozole tablets and for 2 weeks after your last dose of anastrozole tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take:

- **tamoxifen.** You should not take **anastrozole tablets** if you take tamoxifen. Taking anastrozole tablets with tamoxifen may lower the amount of anastrozole tablets in your blood and may cause anastrozole tablets not to work as well.
- **Medicines that contain estrogen.** Anastrozole tablets may not work if taken with any of these medicines:
 - hormone replacement therapy
 - birth control pills
 - estrogen creams
 - vaginal rings
 - vaginal suppositories

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take anastrozole tablets?

- Take anastrozole tablets exactly as your healthcare provider tells you to take it.
- Continue taking anastrozole tablets until your healthcare provider tells you to stop.
- Anastrozole tablets can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Take your next regularly scheduled dose. Do not take two doses at the same time.

If you take too much anastrozole tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of anastrozole tablets?

Anastrozole tablets may cause serious side effects including:

- See “**What is the most important information I should know about anastrozole tablets?**”
- **bone thinning or weakness (osteoporosis).** Anastrozole tablets lowers estrogen in your body, which may cause your bones to become thinner and weaker. This may increase your risk of fractures, especially of your spine, hip and wrist. Your healthcare provider may order a bone mineral density test before you start and during treatment with anastrozole tablets to check you for bone changes.
- **increased blood cholesterol (fat in the blood).** Your healthcare provider may do blood tests to check your cholesterol while you are taking anastrozole tablets.
- **skin reactions.** Stop taking anastrozole tablets and call your healthcare provider right away if you get any skin lesions, ulcers, or blisters.
- **severe allergic reactions.** Get medical help right away if you get:
 - swelling of your face, lips, tongue, or throat
 - trouble swallowing or breathing
- **liver problems.** Anastrozole tablets can cause inflammation of your liver and changes in liver function blood tests. Your healthcare provider may check you for this.

Stop taking anastrozole tablets and call your healthcare provider right away if you have any of these signs or symptoms of a liver problem:

- a general feeling of not being well
- yellowing of your skin or whites of your eyes
- pain on the right side of your stomach-area (abdomen)

Common side effects in women taking anastrozole tablets include:

- hot flashes
- weakness
- joint aches
- joint pain, stiffness or swelling (arthritis)
- pain
- sore throat
- high blood pressure
- depression
- nausea and vomiting
- rash
- back pain
- sleep problems
- bone pain
- headache
- swelling of your legs, ankles, or feet
- increased cough
- shortness of breath
- build up of lymph fluid in the tissues of your affected arm (lymphedema)

Anastrozole tablets may also cause you to have tickling, tingling or numbness of your skin.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of anastrozole tablets. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store anastrozole tablets?

- Store anastrozole tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep anastrozole tablets and all medicines out of the reach of children.

General information about the safe and effective use of anastrozole tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take anastrozole tablets for a condition for which it was not prescribed. Do not give anastrozole tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about anastrozole tablets that is written for health professionals. For more information, call 1-800-367-3395 or go to www.bpirx.com.

What are the ingredients in anastrozole tablets?

Active ingredient: anastrozole, USP

Inactive ingredients: hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, sodium starch glycolate, and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Natco Pharma Limited.

Visakhapatnam - 531019

AP, India.

Distributed by:

Breckenridge Pharmaceutical, Inc.

Berkeley Heights, NJ 07922

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Revised: 12/2023